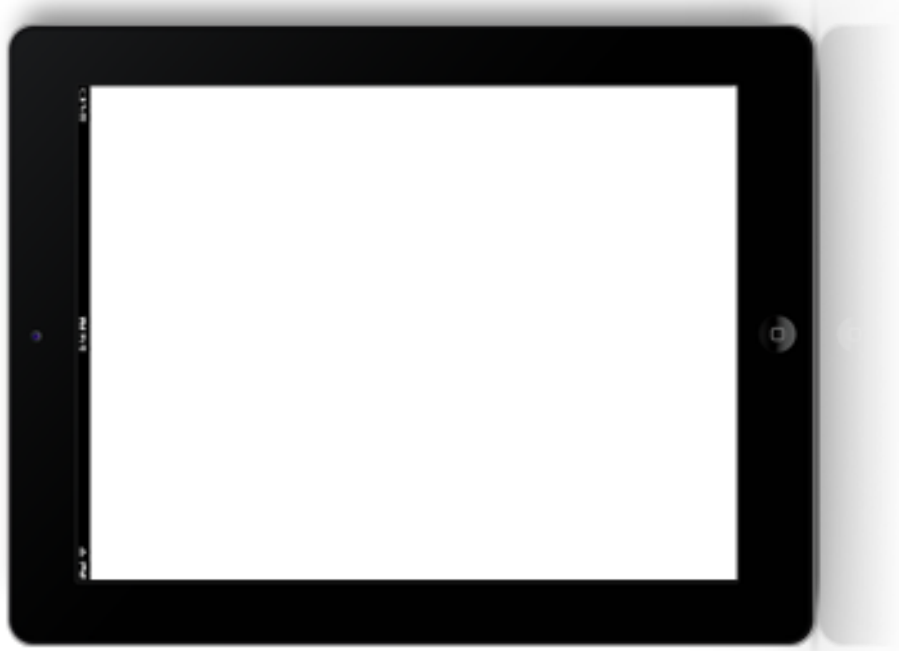


- 7.1 Resources
- 7.2 Competence
- 7.3 Awareness
- 7.4 Communication
- 7.5 Documented information

7. SUPPORT

Resources needed for the Quality Management System

7.1 Resources

- 7.1.1 General
- 7.1.2 People
- 7.1.3 Infrastructure
- 7.1.4 Environment for the operation of processes
- 7.1.5 Monitoring and measuring resources
- 7.1.6 Organizational knowledge

7.1 Resources

7.1.1 General

determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the QMS.

The organization shall consider:

a) the capabilities of, and constraints on, existing internal resources;

b) what needs to be obtained from external providers.

7.1 Resources

7.1.2 People

determine and provide

- persons necessary for the effective implementation of its QMS
- and for the operation and control of its processes

7.1 Resources

7.1.3 Infrastructure

determine, provide and maintain

- infrastructure necessary for the operation of its processes and
- to achieve conformity of products and services.

Infrastructure can include:
a) buildings and associated utilities
b) equipment - hardware and software
c) transportation resources
d) IT and communication technology.

7.1 Resources

7.1.4 Environment for the operation of processes

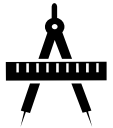
determine, provide and maintain the environment necessary

- for the operation of its processes
- and to achieve conformity of products and services.

NOTE A suitable environment can be a combination of human and physical factors, such as:
a) social b) psychological c) physical

7.1 Resources

7.1.5 Monitoring and measuring resources



7.1.5.1 General

- determine and provide the resources needed to ensure valid and reliable results

7.1.5.2 Measurement traceability

- Requirements related to measuring equipment when measurement traceability is a requirement, or is an essential part of providing confidence in the validity of measurement results

definition

TRACEABILITY

ability to trace the history, application or location of an object

7.1 Resources

7.1.5 Monitoring and measuring resources

7.1.5.1 General

determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity

The organization shall ensure that the resources provided:

a) are suitable
b) are maintained

retain appropriate documented information as evidence of fitness for purpose

7.1 Resources

7.1.5 Monitoring and measuring resources

7.1.5.2 Measurement traceability

When measurement traceability

- is a requirement,
- or is considered by the organization to be an essential part of providing confidence in the validity of measurement results,

measuring equipment shall be:

a) Calibrated or verified or both
b) identified
c) safeguarded

7.1 Resources

7.1.5 Monitoring and measuring resources

7.1.5.2 Measurement traceability

The organization shall determine

- if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose,

- and shall take appropriate action as necessary.

7.1 Resources

7.1.6 Organizational knowledge

The organization shall determine the knowledge necessary

- for the operation of its processes and
- To achieve conformity

This knowledge shall be maintained and be made available to the extent necessary.

7.1 Resources

7.1.6 Organizational knowledge

When addressing changing needs and trends,

- the organization shall consider its current knowledge and
- determine how to acquire or access any necessary additional knowledge and required updates.

7.2 Competence

- a) determine the necessary competence of person(s)
- b) ensure that these persons are competent
- c) take actions to acquire the necessary competence, and evaluate effectiveness
- d) retain appropriate documented information as evidence of competence.

7.3 Awareness

The organization shall ensure that persons doing work under the organization's control are aware of:

- a) the quality policy
- b) relevant quality objectives
- c) their contribution to the effectiveness of the QMS
- d) the implications of not conforming with the QMS requirements.

7.4 Communication

The organization shall determine the internal and external communications relevant to the QMS, including:

- a) on what it will communicate;
- b) when to communicate;
- c) with whom to communicate;
- d) how to communicate;
- e) who communicates.

7.5 Documented information

- 7.5.1 General
- 7.5.2 Creating and updating
- 7.5.3 Control of documented information

7.5 Documented information

7.5.1 General

The organization's QMS shall include:

- a) documented information required by this International Standard;
- b) documented information determined by the organization necessary for the effectiveness of the QMS.

NOTE: The extent of documented information for a quality management system can differ from one organization to another.

definition

DOCUMENT

information and the medium on which it is contained

definition

DOCUMENTED INFORMATION

information required to be controlled and maintained by an organization and the medium on which it is contained

7.5 Documented information

7.5.2 Creating and updating

When creating and updating documented information, the organization shall ensure appropriate:

- a) identification and description
- b) format and media
- c) review and approval for suitability and adequacy.

7.5 Documented information

7.5.3 Control of documented information

7.5.3.1

Documented information required by the QMS and by this International Standard shall be controlled to ensure:

a) it is available and suitable for use, where and when it is needed;

b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

7.5 Documented information

7.5.3 Control of documented information

7.5.3.2

For the control of documented information, address the following activities, as applicable:

- a) distribution, access, retrieval and use;
- b) storage and preservation, including preservation of legibility;
- c) control of changes (e.g. version control);
- d) retention and disposition.

7.5 Documented information

7.5.3 Control of documented information

- Documented information of external origin determined by the organization to be necessary for the planning and operation of the QMS shall be identified as appropriate, and be controlled.

- Documented information retained as evidence of conformity shall be protected from unintended alterations.